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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,898	02/09/2004	Robert A. Rabiner	20563/2432	8765

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EXAMINER

LUONG, PETER

ART UNIT	PAPER NUMBER
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3709

MAIL DATE	DELIVERY MODE
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08/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/774,898

Applicant(s)

RABINER ET AL.

Examiner

Peter Luong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/21/2004, 09/13/2004, and 10/02/2006.

DETAILED ACTION

Claim Objections

1. Claims 1, 24, 34-41, 45, 53, 55, and 57-60 are objected to because of the following informalities: With respect to claims 34-41, 45, 53, and 57-60, "the transverse vibration" should be --a transverse vibration--, with respect to claim 55, "the ultrasonic probe" should be --the flexible probe--, and the term "ultrasonic energy source" in claims 1, 24, 34, and 55 is used by the claim to mean "an electrical energy", while the accepted meaning is "an acoustic energy." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 4-11, 13, 25, 27-29, 35, 37-41, 44-47, and 56-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant claims vibrations in which are induced, tuned, shifted, segregated, or superimposed with a combination of vibrations. The applicant also claims a torsional vibration that causes rotation and counter-rotation and forward and reverse propagation. The applicant further claims a plurality of nodes and anti-nodes along the longitudinal axis of the probe. However, the applicant fails to disclose a particular structure or feature in the present application that

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enables one of ordinary skill in the art to produce such vibrations in a reproducible manner without undue experimentation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-36, 40, 42-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuris (US 3,565,062 - cited in IDS). The patent of Kuris discloses a **medical device (abstract) comprising an elongated, flexible probe (43, col. 3, ln. 35-36) comprising a proximal end (45), a distal end (50) and a longitudinal axis (it is inherent that two ends of a tubular structure would have an axis associated along its length) between the proximal end (45) and the distal end (50); a transducer (41, col. 6, ln. 36-39, a piezoelectric material) that converts electrical energy into mechanical energy (it is inherent that a piezoelectric material converts electrical energy into mechanical energy and vice versa) creating a torsional vibration (col. 4, ln. 44-49) along the longitudinal axis of the elongated, flexible probe (43), a coupling (42) engaging the proximal end (45) of the elongated, flexible probe (43) to a distal end (50) of the transducer (41), and an ultrasonic energy source (36) engaged to the transducer (41) that provides the electrical energy to the transducer (41), wherein the examiner takes the position that the longitudinal axis of the elongated, flexible**

probe (43) inherently supports the torsional vibration and a transverse vibration

(col. 4, ln. 44-49, see MPEP 2112).

6. With respect to claims 2, 4-8, 10, 25, 27-29, 35, 41, 46, 56, and 59-60, there are no structural differences between the device of Kuris and the present application.

Therefore, the device of Kuris is capable of producing the variations of torsional and transverse vibrations (i.e. inducing, tuning, shifting, segregating, or superimposing) as claimed in the present application.

7. With respect to claims 3, 18, 26, 36, 42, and 53-54, it is inherent that since the device of Kuris is an ultrasonic probe, it will support vibrations, as the purpose of the device is to transmit vibrations from the probe to the surrounding area (see MPEP 2112).

8. With respect to claims 9, 11, 13, 44-45, and 47, there are no structural differences between the device of Kuris and the present application. Therefore, the device of Kuris is capable of producing the variations of nodes and anti-nodes (col. 6, ln. 17-21).

9. With respect to claims 12, 14-15, 43, 61, Kuris also discloses that **the torsional vibration and the transverse vibration (col. 4, ln. 44-49) generate acoustic energy in a medium (17) surrounding the ultrasonic probe (43) through an interaction of a surface (50) of the ultrasonic probe (43) and the medium (17) surrounding the ultrasonic probe (43) (i.e. transmits to the vascular system, col. 2, ln. 39-47).**

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10. With respect to claim 16 and 51, Kuris discloses **the ultrasonic energy source (36) delivers ultrasonic energy in a frequency range from about 1 kHz to 1000 kHz** (col. 3, ln. 5-8) that encompasses the claimed range of **10 to 100 kHz**.

11. With respect to claim 17 and 52, Kuris discloses that **the ultrasonic energy source determines (36) a resonant frequency of the transducer (41) and provides an electrical power to the transducer (41) at the resonant frequency of the transducer (41)** (col. 6, ln. 5-11).

12. With respect to claims 19-20, 22-23, 30, 63-67, and 70-71, Kuris discloses that **the ultrasonic probe (43) comprises an approximately circular cross section (fig. 11, claim 14) from the proximal end (45) of the ultrasonic probe (43) to the distal end (50) of the ultrasonic probe (43) and the ultrasonic probe (43) comprises a varying cross section from the proximal end (45) of the ultrasonic probe (43) to the distal end (50) of the ultrasonic probe (43)** (fig 10, 51c).

13. With respect to claims 21 and 68-69, Kuris discloses **a portion of the longitudinal axis of the ultrasonic probe comprises a radially asymmetric cross section** (the cross section of the tip gradually decrease in size and there is a stepwise decrease in cross section from the tubular catheter to the probe, fig. 10).

14. With respect to claims 32 and 73, it is within the level of ordinary skill in the art to dispose of an old or broken probe at a one point in time, furthermore it is recognized as an intended use in.

15. With respect to claims 33 and 74, it is recognized that during a surgical procedure the surgical device is used on the patient undergoing the procedure,

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furthermore it is recognized as an intended use in which the device of Kuris is capable of performing.

16. With respects to claims 34-36, 40, 42-47 and 51-61, the device of Kuris inherently discloses the method steps substantially as claimed.

17. With respect to claim 48-50, Kuris discloses the method step of moving the probe back, rotating the probe, and repositioning the probe to provide a new exposed area (col. 9, ln. 68-74).

18. With respect to claim 72, it is inherent that a flexible probe is capable of being deflected and articulated (see MPEP 2112).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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21. Claims 37-39 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuris (US 3,565,062 - cited in IDS) in view of McCullough et al. (US 6,723,451).

22. The patent of Kuris discloses all the claimed subject matter with the exception of the method steps of tuning the vibrations.

23. However the patent of McCullough et al. teaches the method of tuning an ultrasonic horn by altering its length (column 14, lines 35-36). One of ordinary skill in the art would recognize that bending (therefore applying tension) constitutes as altering length. Therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the methods taught in Kuris in view of the teaching of McCullough to obtain a desired vibration frequency (column 14, lines 35-36).

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ams et al., Dubrul et al., Fenton et al., and Wuchinich, cited in the IDS, all disclose ultrasonic devices that operate in both torsional and transverse modes for the removal of biological material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571) 270-1609. The examiner can normally be reached on Monday - Thursday, 7:30 a.m. - 5:00 p.m., EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on (571) 272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Terrence R. Till
Supervisory Patent Examiner



P.L.